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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,114	02/09/2001	Tsutomu Nobori	023070103031	8926

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/14/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,114	NOBORI ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed June 30, 2002. Currently, claims 10-16 are pending. Claims 10, 12-16 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election of Group I, Claim 11 in Paper No. 17 is acknowledged. The response asserts that Groups I-III all stem from a common concept and are thus related. As discussed in MPEP 803, one of the two criteria for requirement of restriction is that the "inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed". Accordingly, the demonstration of distinctness of the inventions is sufficient grounds for restriction. Applicants further argue that it would not be an undue burden to examine the claims of all groups I-III. However, it is maintained that undue burden would be required to examine the claims of groups II, III along with the claims of group I as evidenced by the fact that the claims of groups I, II, III have acquired a separate status in the art as recognized by their different classification and as recognized by their divergent subject matter and because a search of the subject matter of invention 1 is not co-extensive with a search of inventions II-III. The response cites MPEP 803 which requires the examiner to show that the restricted groups have a separate classification, or separate status in the art. As provided in the restriction requirement each of the groups has both a separate classification and separate status in the art. Therefore, the argument is not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10, 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

Priority

3. This application claims priority to 09/072,914, 08/827,342, 08/459,343, 08/176,855.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

As provided in the MPEP 201.11, "Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. **This reference must be submitted during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. This time period is not extendable.** Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following the title."

The instant first line of the specification does not contain reference to application number 08/827,342. The ADS sheet does not contain any priority information.

Moreover, the request for Corrected filing receipt appears to be incorrect since it does not appear that 08/176,855 is a division of 08/827,342. Regardless, this claim to priority

has not been made within four months of the actual filing date of the application or within 16 months of the filing date of the prior application.

Moreover, 08/459,343 filed in 1995 is not a CIP of 08/827,342, filed in 1997. The earlier filed application can not be a parent application. Appropriate correction is required.

With respect to Claim 11, the Claim is awarded priority to the filing date of 3/26/97 for the invention of a nucleic acid sequence having SEQ ID NO: 1 which encodes the MTase. The 08/459,343 application, filed 6/2/95, which is a divisional of 08/176,855. disclosed SEQ ID NO: 1 containing a partial genomic sequence of the MTase gene and therefore did not encode MTase (since it did not contain all of the sequences indicated as coding sequences in Figure 1 and SEQ ID NO: 1 of the present application).

Specification

4. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed. A suggested title is: Nucleic Acids encoding MTase.

Claim Objections

5. Claim 11 is objected to because of the following informalities: Claim 11 depends upon Claim 7 which has been cancelled. Claim 11 is not a complete claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 11 is indefinite because Claim 11 depends from a cancelled claim. In the interest of providing applicant an office action, Claim 11 has been read to include the previously pending Claim 7 limitations. Moreover, Claim 11 is indefinite in the recitation of "peptide encoding fragments" as it is unclear what the metes and bounds of a fragment is (anything encoding two amino acids or more?) and further what relationship the peptide encoding fragments had to each other within the vector (i.e. it is not clear if the expression vector ultimately expresses MTase since the peptide fragments are not recited as being provided in any particular order). The limitations "Sequence listing appended hereto as SEQ ID NO: 1" in Claim 7 because the sequence listing is provided before the claims so the reference to "appended hereto" is confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Olopade et al (PNAS Vol. 92, pages 6489-6493, July 1995).

It is noted that since the priority of Claim 11 is 3/26/97, the instant rejection is applicable.

Olopade et al teaches the cloning of the cDNA of the methylthioadenosine phosphorylase gene which encodes the methyladenosine phosphorylase protein (see Figure 3, page 6492) (MTAP and MTase are the same protein). CDNAs were taught as having been cloned into lambda gt 10 or gt11 (lambda gt 11 is an expression vector) and subcloned into bluescript (also an expression vector) for sequencing (see page 6490, col. 2). The sequence of Olopade is interpreted as being substantially similar to the sequence contained in SEQ ID NO: 1 and the expression vectors taught by Olopade are interpreted as containing peptide encoding fragments of the polynucleotide of Claim 7 (the fragments in this case are the exons). Olopade et al also teaches YAC clones, A73B12 and 802B11 which include the MTAP gene and therefore, inherently

"have" the nucleic acid sequence shown as SEQ ID NO: 1 and inherently encode MTase.

8. Claim 11 is rejected under 35 U.S.C. 102(a) as being anticipated by Nobori et al (PNAS Vol. 93, pages 6203-6208, June 1996).

Nobori et al. (herein referred to as Nobori) teaches subcloning DNA from phage and cosmid clones into pBluescript, an expression vector (page 6204) (cDNA and genomic cloning of MTAP gene). Figure 2 of Nobori teaches the DNA sequences of the protein-coding exons and their flanking regions in the human MTAP gene (page 6205). Since the nucleic acids cloned into said vector inherently contain codons of the gene; the expression vector is interpreted as "containing peptide encoding fragments" of the polynucleotide of Claim 7.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 9 of U.S. Patent No. 5,942,393, August 24, 1999. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sequence recited in Claim 7, 9 of the '113 application, having the nucleotide sequence shown in SEQ ID NO: 1, or comprising only the exon coding regions of the nucleic acid sequence of Figure 1 is the same sequence required in cancelled Claim 7, from which Claim 11 depends. Claims 7 and 9 of '113 recites an expression vector containing the polynucleotide of Claim 6 and therefore as the claim encompasses an expression vector which comprises exon coding regions of the nucleic acid sequence of Figure 1, inherently contains peptide encoding fragments of the polynucleotide of Claim 7, as require by instant Claim 11.

Conclusion


10. No claims allowable over the art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
August 10, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600